

Sullivan
11-5-80

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

YASUhide TACHI et al

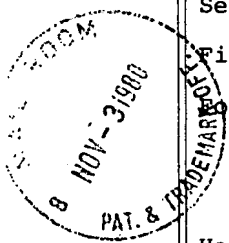
Serial No. 024,111

Group: 125

Filed: March 26, 1979

Examiner: Roberts

For: NOVEL HYDROCORTISONE DERIVATIVE



DECLARATION

Honorable Commissioner of Patents and Trademarks
Washington, D. C. 20231

Sir:

I, JIRO SAWADA, hereby declare the following:

1. I am a citizen of Japan residing at 6-105, Hanakoganei, Kodaira, Tokyo, Japan. I received a Doctorate of Agriculture Degree from Kyushu University in March 1965 and have been employed by TAISHO PHARMACEUTICAL CO., LTD. since April, 1953.

2. I am one of the co-inventors of the captioned application.

3. As urged by the examiner in connection with the captioned application (p. 3 of office action of July 3, 1980) tests were conducted under my personal supervision to compare the therapeutic effectiveness of betamethasone 17-valerate-21-acetate with that of betamethasone 17-butyrate-21-propionate (example 29 of Elks '590).

The above two compounds were tested for effectiveness as vasoconstrictors using the procedure described at p. 4, lines 15-27, of our specification, i.e. each compound was admixed with petrolatum to make up a 0.1% ointment and each of the two ointments was randomly applied to the forearms of 30 healthy adult male volunteers and removed at 4 hours after application. The degrees

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of vasoconstriction were scored as described at p. 4, lines 19-27 of our specification. The results were as follows:

<u>Compound</u>	<u>Average Score</u>
Betamethasone-17-Butyrate-21-propionate	2.19
Betamethasone-17-Valerate-21-acetate	2.27

Thus, of the two compounds, Betamethasone-17-Valerate-21-acetate proved to be the more effective vasoconstrictor.

4. I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Jiro Sawada

JIRO SAWADA

Date: October 22, 1980.